

## **REMARKS/ARGUMENTS**

Claims 1-11 are pending in the present application. Claims 1, 6-7 and 11 have been amended, and claims 12-13 have been cancelled. For at least the reasons that follow, Applicant submits that claims 1-11, as amended, are in condition for allowance.

### ***Informalities***

The acronyms in claims 6, 7 and 11 (4ASA, 4-ASA, 5ASA, 5-ASA and 4-ABA) have been spelled out.

The abstract of the disclosure has been presented on a separate sheet of paper without other parts of the application or other material.

### ***35 U.S.C. § 112, Second Paragraph (Indefiniteness)***

Claims 1 and 11 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the stated reason that the metes and bounds of “or other non-specific bowel disorder” cannot be precisely determined. Claims 1 and 11 have been amended to recite particular non-specific non-inflammatory bowel disorders from the specification. Applicant respectfully submits that claims 1 and 11, as amended, are not indefinite.

Claim 3 is stated to lack clarity because it recites conditions that characterize both non-inflammatory diseases as well as inflammatory intestinal disorders. Claim 1, as amended, is limited to non-inflammatory intestinal disorders. As claim 3 is dependent on amended claim 1, the conditions recited in claim 3 characterize only non-inflammatory diseases. Applicant therefore respectfully submits that claim 3, as dependent on amended claim 1, does not lack clarity.

The parenthetical subject matter recited in claim 7 is stated to render the claim indefinite. The parenthetical subject matter (“(4-amino salicylic acid)”) has been deleted from the claim. Applicant therefore submits that claim 7, as amended, is not indefinite.

### ***35 U.S.C. § 101***

Claims 12 and 13 stand rejected under 35 U.S.C. § 101. Claims 12 and 13 have been cancelled.

### ***35 U.S.C. § 112, First Paragraph (Written Description)***

Claims 1 and 11 stand rejected under 35 U.S.C. § 112, first paragraph, for the stated reason that the phrase “a derivative thereof” lacks adequate written description support. The phrase “or a derivative” has been deleted from claims 1

and 11. Applicant therefore respectfully submits that claims 1 and 11, as amended, comply with the written description requirement.

***35 U.S.C. § 112, First Paragraph (Enablement)***

Claims 1-13 stand rejected under 35 U.S.C. § 112, first paragraph, for the stated reason that the specification does not reasonably provide enablement for methods of “prophylaxis” within the full scope of the claims. The Office Action acknowledges, however, that the specification provides enabling support for the prophylaxis of irritable bowel syndrome. (Page 7.) Independent claims 1 and 11 have been amended such that they are now directed to a method for the prophylaxis of irritable bowel syndrome or for the treatment of non-inflammatory bowel diseases, diarrhoea-predominant irritable bowel syndrome and the other recited non-specific non-inflammatory bowel disorders. Applicant therefore respectfully submits that amended claims 1 and 11, as well as the claims that depend therefrom, are enabled by the specification.

***Obviousness-Type Double Patenting***

Claim 11 stands rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 8 and 9 of U.S. Patent

No. 5,519,014. Applicant requests reconsideration of this rejection in view of the amendments made to Claim 11.

***35 U.S.C. § 103 (Obviousness)***

Claims 1-10, 12 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilson et al. (WO 2005/030173). Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilson in view of Lin et al. (U.S. Patent No. 6,326,364).

Applicant thanks the Examiner for the courtesy extended during a short telephonic interview on July 18, 2008. During the interview, Applicant questioned how Wilson was determined to be prior art to the present application. The Examiner explained that Wilson was prior art as of its priority date under 35 U.S.C. 102(e)/103. Applicant respectfully continues to question the status of Wilson as prior art to the present application. Specifically, Applicant questions how an international application can be prior art to the present application as of its priority date when the priority application was not published as of Applicants' priority date (and has never been published).

In any event, Applicant respectfully submits that Wilson is distinguishable from the presently claimed subject matter. Independent claims 1 and 11, as amended, are limited to non-inflammatory intestinal disorders. Wilson is directed

to colon-specific drug delivery using interpolymer complexations. The pharmaceutically active agent may be balsalazide amongst a number of other agents such as glucocorticoids. The drug delivery system may be used to treat constipation, irritable bowel syndrome (IBS), Crohn's disease, ulcerative colitis, carcinomas and colorectal cancer amongst others.

Wilson contains, however, no specific teaching of the use of balsalazide to treat non-inflammatory bowel diseases. Indeed, the Background section of Wilson states:

Colon diseases include conditions such as Crohn's disease, colitis (particularly ulcerative colitis), irritable bowel syndrome and the like. These diseases include a spectrum of *inflammatory bowel disorders* . . . . Both Crohn's disease and ulcerative colitis are characterized by *chronic inflammation* at various sites of the gastrointestinal tract . . . . In treating these disease states, it is difficult to direct drugs that are specifically *anti-inflammatory* in nature and act topically at the desired site.

(Pages 1-2 (emphasis added).) Applicant thus submits that Wilson is distinct from the present claims, which are limited to non-inflammatory intestinal disorders. For this reason, the present claims are patentable over Wilson, whether considered alone or in combination with Lin.

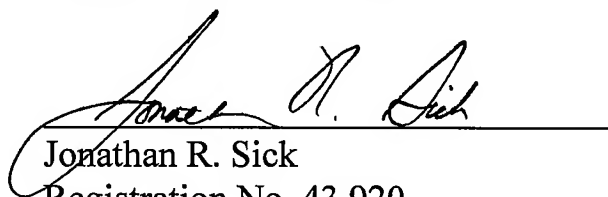
## ***Conclusion***

For the foregoing reasons, the Examiner is respectfully requested to prepare a Notice of Allowability allowing all the pending claims 1-11.

If the Examiner has any questions or the Applicant can be of any assistance, the Examiner is invited and encouraged to contact the Applicant at the number below.

Please charge any required fees, or credit any overpayment, incurred in connection with this submission to Deposit Account No. 13-0017.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jonathan R. Sick", is written over a horizontal line.

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